

HOUSE BILL 137

By Sexton C

AN ACT to amend Tennessee Code Annotated, Title 56;  
Title 63 and Title 68, relative to a prescription drug  
donation repository program.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 63, Chapter 10, is amended by deleting  
part 5 and substituting the following:

**63-10-501.**

As used in this part:

(1) "Anti-rejection drug" means a prescription drug that suppresses the  
immune system to prevent or reverse rejection of a transplanted organ;

(2) "Board" means the board of pharmacy;

(3) "Cancer drug" means a prescription drug that is used to treat any of  
the following:

(A) Cancer or the side effects of cancer; or

(B) The side effects of any prescription drug that is used to treat  
cancer or the side effects of cancer;

(4) "Controlled substance" means the same as defined in § 39-17-402;

(5) "Department" means the department of health;

(6) "Indigent" means a person with an income that is below two hundred  
percent (200%) of the federal poverty level as defined by the most recently  
revised poverty income guidelines published by the United States department of  
health and human services;

(7) "Medical facility" means any of the following:

- (A) A physician's office;
- (B) A hospital;
- (C) A health clinic;
- (D) A nonprofit health clinic, which includes a federally qualified health center as defined in 42 U.S.C. § 1396d(l)(2)(B); a rural health clinic, as defined in 42 U.S.C. § 1396d(l)(1); and a nonprofit health clinic that provides medical care to patients who are indigent, uninsured, or underinsured;
- (E) A free clinic as defined in § 63-6-703;
- (F) A charitable organization as defined in § 48-101-501; or
- (G) A nursing home as defined in § 68-11-201;
- (8) "Pharmacy" means a pharmacy as defined in § 63-10-204;
- (9) "Prescription drug" means the same as defined in § 63-10-204, and includes cancer drugs and anti-rejection drugs, but does not include controlled substances; and
- (10) "Supplies" means the supplies necessary to administer the prescription drugs donated.

**63-10-502.**

- (a) The board of pharmacy, in cooperation with the department of health, may establish and maintain a prescription drug donation repository program under which any person may donate prescription drugs and supplies for use by an individual who meets eligibility criteria specified by the board by rule. The board may contract with a third party to implement and administer the program.
- (b) Donations of prescription drugs and supplies under the program may be made on the premises of a medical facility or pharmacy that elects to participate in the program and meets the requirements established by the board.

(c) The medical facility or pharmacy may charge an individual who receives a prescription drug or supplies a handling fee that does not exceed an amount established by rule by the department.

(d) A medical facility or pharmacy that receives prescription drugs or supplies may distribute the prescription drugs or supplies to another eligible medical facility or pharmacy for use pursuant to the program.

(e) Participation in the program is voluntary.

**63-10-503.**

(a) A prescription drug or supplies may be accepted and dispensed under the prescription drug donation repository program if all of the following conditions are met:

(1) The prescription drug is in its original sealed and tamper-evident packaging. However, a prescription drug in a single-unit dose or blister pack with the outside packaging opened may be accepted if the single-unit dose packaging remains intact;

(2) The prescription drug bears an expiration date that is more than six (6) months after the date the prescription drug was donated;

(3) The prescription drug or supplies are inspected before the prescription drug or supplies are dispensed by a licensed pharmacist employed by or under contract with the medical facility or pharmacy, and the licensed pharmacist determines that the prescription drug or supplies are not adulterated or misbranded; and

(4) The prescription drug or supplies are prescribed by a healthcare practitioner for use by an eligible individual and are dispensed by a pharmacist.

(b) A prescription drug or supplies donated under this part shall not be resold.

(c)

(1) If a person who donates prescription drugs under this part to a medical facility or pharmacy receives a notice from a pharmacy that a prescription drug has been recalled, the person shall inform the medical facility or pharmacy of the recall.

(2) If a medical facility or pharmacy receives a recall notification from a person who donated prescription drugs under this part, the medical facility or pharmacy shall perform a uniform destruction of all of the recalled prescription drugs in the medical facility or pharmacy.

(d) A prescription drug dispensed through the prescription drug donation repository program is not eligible for reimbursement under the medical assistance program.

(e) The board shall adopt rules establishing all of the following:

(1) Requirements for medical facilities and pharmacies to accept and dispense donated prescription drugs and supplies, including all of the following:

(A) Eligibility criteria for participation by medical facilities and pharmacies;

(B) Standards and procedures for accepting, safely storing, and dispensing donated prescription drugs and supplies;

(C) Standards and procedures for inspecting donated prescription drugs to determine if the prescription drugs are in their original sealed and tamper-evident packaging, or if the prescription drugs are in single-unit doses or blister packs and the outside packaging is opened, if the single-unit dose packaging remains intact; and

(D) Standards and procedures for inspecting donated prescription drugs and supplies to determine that the prescription drugs and supplies are not adulterated or misbranded;

(2) Eligibility criteria for individuals to receive donated prescription drugs and supplies dispensed under the program. The standards shall prioritize dispensing to individuals who are indigent or uninsured, but may permit dispensing to other individuals if an uninsured or indigent individual is unavailable;

(3) Necessary forms for administration of the prescription drug donation repository program, including forms for use by individuals who donate, accept, distribute, or dispense the prescription drugs or supplies under the program;

(4) A means by which an individual who is eligible to receive donated prescription drugs and supplies may indicate eligibility;

(5) The maximum handling fee that a medical facility or pharmacy may charge for accepting, distributing, or dispensing donated prescription drugs and supplies under the program; and

(6) A list of prescription drugs that the prescription drug donation repository program will accept.

**63-10-504.**

(a) A drug manufacturer acting reasonably and in good faith, is not subject to criminal prosecution or civil liability for injury, death, or loss to a person or property for matters related to the donation, acceptance, or dispensing of a prescription drug manufactured by the drug manufacturer that is donated under this part, including liability for failure to transfer or communicate product or consumer information or the expiration date of the donated prescription drug.

(b) Except as provided in subsection (c), a person other than a drug manufacturer subject to subsection (a), acting reasonably and in good faith, is immune from civil liability and criminal prosecution for injury to or the death of an individual to whom a donated prescription drug is dispensed under this part and is exempt from disciplinary action related to the person's acts or omissions related to the donation, acceptance, distribution, or dispensing of a donated prescription drug under this part.

(c) The immunity and exemption provided in subsection (b) do not extend to the following:

(1) The donation, acceptance, distribution, or dispensing of a donated prescription drug under this part by a person if the person's acts or omissions are not performed reasonably and in good faith; or

(2) Acts or omissions outside the scope of the program.

**63-10-505.**

This part shall not restrict the use of samples by a physician or other person legally authorized to prescribe drugs pursuant to this title during the course of the physician's or other person's duties at a medical facility or pharmacy.

**63-10-506.**

This part does not authorize the resale of prescription drugs by any person.

**63-10-507.**

The board of pharmacy is authorized to promulgate rules to effectuate the purposes of this part. The rules shall be promulgated in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

SECTION 2. If any provision of this act or its application to any person or circumstance is held invalid, then the invalidity shall not affect other provisions or applications of the act that

can be given effect without the invalid provision or application, and to that end the provisions of this act shall be severable.

SECTION 3. This act shall take effect upon becoming a law for purposes of rulemaking and on January 1, 2017, for all other purposes, the public welfare requiring it.